



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0302; FRL-9377-6]

Acetochlor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends inadvertent tolerances for residues of acetochlor in or on crop groups 15 and 16 for cereal grains by dropping the exclusion for rice grain and straw. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0302, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Hope Johnson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5410; email address: johnson.hope@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0302 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0302, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F7996) by Monsanto Company, 1300 I St., NW., Suite 450 East, Washington DC 20005. The petition requested revisions to the current tolerances for residues of the herbicide acetochlor, 2-chloro-2'-methyl-6'-ethyl-*N*-ethoxymethylacetanilide and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl)-6-methyl-aniline (HEMA) moiety, at 40 CFR 180.470 for grain, cereal, group 15, except corn, grain sorghum, rice, and wheat, grain and grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw.

Specifically the petition requested that crop groups 15 and 16 be amended by dropping the exception for rice grain and rice straw, respectively. That document referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

III. Tolerance Level

Monsanto sought the removal of the exception for rice and rice straw for the acetochlor tolerances for crop groups 15 and 16 so that rice crops could be rotated to fields previously treated with acetochlor. EPA determined that this revision to these tolerances was appropriate without modifying the tolerance value based upon translation of residue data reflecting analysis for residues of acetochlor and its metabolites in/on wheat and sorghum commodities planted after treatment with acetochlor. Residues in the wheat and sorghum grain were non-quantifiable, whereas finite residues that were below the existing crop group tolerance were reported in the straw.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other

relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetochlor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetochlor follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetochlor has low acute toxicity by the oral, dermal, and inhalation routes of exposure and is mildly irritating to the eyes. The results of two dermal irritation studies indicate that it is a mild to strong skin irritant. Acetochlor is also a strong dermal sensitizer.

Evidence of neurotoxicity was observed in acute and subchronic neurotoxicity screening studies in rats, developmental toxicity studies in rats, and subchronic and chronic studies in dogs. In addition to the nervous system, the major target organs affected in subchronic and chronic studies in rats, dogs, and mice exposed to acetochlor are the liver, thyroid (secondary to liver), kidney, testes, and erythrocytes. Species-specific target organs include the nasal olfactory epithelium in rats and the lungs in mice. There is no evidence of increased qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in the developmental and reproduction toxicity studies in rats and rabbits. In two developmental toxicity studies in rats, fetal effects (increased

early resorptions, post-implantation loss, and decreased fetal weight) occurred at doses that also resulted in maternal toxicity (mortality, clinical signs of toxicity, and decreased maternal body weight gain). In two rabbit developmental toxicity studies there were no adverse fetal effects at the highest doses tested (HDT) (190 milligrams/kilograms/day (mg/kg/day) and 300 mg/kg/day); whereas maternal toxicity (body weight loss) was seen at 50 mg/kg/day in one study. In three reproduction toxicity studies in rats, offspring effects (decreased pup weights in the first two studies; decreased pup weights, decreased F2 litter size at birth, and focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study) occurred at the same or higher doses than those resulting in parental toxicity (decreased body weight or weight gain in the first two studies; focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study). There was no evidence of reproductive toxicity observed at any dose tested in two of the three reproductive toxicity studies in rats. The third reproduction study in rats showed a decreased number of implantations at the HDT of 1,750 parts per million (ppm).

EPA has determined that quantification of carcinogenic risk on a linear, non-threshold basis is not appropriate for the mouse tumors. There are acceptable mode of action data for the rat tumors (nasal olfactory epithelial tumors and thyroid follicular cell tumors) which are adequate to support a non-linear, threshold approach for assessment of cancer risk. The rat nasal tumors are the most sensitive effect for cancer risk. However, because rat nasal tumors are not the most sensitive chronic effect, EPA has not conducted a separate cancer-only risk assessment but performed a single, chronic risk assessment

that will be protective of both non-cancer and cancer effects, including rat nasal tumors, thyroid tumors, and mouse tumors.

Specific information on the studies received and the nature of the adverse effects caused by acetochlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document entitled “Acetochlor Human Health Risk Assessment for Proposed New Use of Acetochlor on Cotton and Soybeans” at page 41 in docket ID number EPA-HQ-OPP-2009-0002.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete

description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for acetochlor used for human risk assessment is discussed in Unit III.A of the final rule published in the **Federal Register** issue of September 16, 2009 (74 FR 47445) (FRL-8434-1).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetochlor, EPA considered exposure under the petitioned-for tolerances as well as all existing acetochlor tolerances in 40 CFR 180.470. EPA assessed dietary exposures from acetochlor in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for acetochlor. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, entitled “What We Eat in America” (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for all commodities. Experimentally derived processing factors were used for cereal grain commodities. Default processing factors were used for all other commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2003-2008 NHANES/WWEIA. As to

residue levels in food, EPA used anticipated residues from field trial data and 100 PCT assumptions for all commodities. Experimentally derived processing factors were used for cereal grain commodities. Default processing factors were used for all other commodities.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or non-linear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or non-linear approach is used and a cancer RfD is calculated based on an earlier non-cancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A., EPA has concluded that a non-linear RfD approach is appropriate for assessing cancer risk to acetochlor. However, cancer-only risk assessment was not conducted because the chronic RfD of 0.02 mg/kg/day will be protective of both non-cancer and cancer effects. The chronic exposure assessment described in Unit IV.C.1.ii. also accurately estimates exposure for the purposes of assessing cancer risk.

iv. *Anticipated residue information.* EPA used anticipated residues derived from the results of field trials in the chronic dietary exposure assessment.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be

provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetochlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetochlor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Acetochlor parent residue exposure is generally higher and more widespread through surface water sources than ground water, therefore, the Agency generated the surface water concentrations using the PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System). The estimated drinking water concentrations (EDWCs) of acetochlor for acute exposures are estimated to be 75 parts per billion (ppb) for drinking water. For chronic exposures for non-cancer assessments are estimated to be 4.8 ppb for drinking water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 75 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 4.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Acetochlor is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

The chloroacetanilides have been evaluated by the Agency and the Federal Insecticides, Fungicides, and Rodenticides Act (FIFRA) Scientific Advisory Panel (SAP) as a related group of chemicals for this purpose. Acetochlor is included in a Cumulative Assessment Group (CAG) of chloroacetanilide pesticides. Structurally related chloroacetanilides include acetochlor, alachlor, butachlor, metolachlor, and propachlor. For purposes of a cumulative risk assessment, it was determined that the common mechanism of toxicity group consists of alachlor, acetochlor, and butachlor. Butachlor is excluded from the group for risk assessment purposes at present because there are no registered uses or tolerances for this chemical in the United States. The group was selected based on common endpoints of:

- Nasal turbinate tumors in rats, and a known mechanism of toxicity for development of these tumors.

- Induction of hepatic Uridine Diphosphate-Glucuronosyl Transferase (UDPGT), which results in increased incidence of thyroid follicular cell tumors secondary to disruption of pituitary-thyroid homeostasis.

Thyroid effects were not included in the final cumulative assessment of the chloroacetanilide herbicides because they were determined to occur at excessively toxic dose levels, and therefore were not considered relevant to human risk assessment. Nasal tumors represent the most sensitive endpoint for both compounds.

An updated cumulative risk assessment of the chloroacetanilide (CAG) pesticides acetochlor and alachlor conducted in April 2007 provides an assessment of existing and new uses of those chemicals to date. Based on the most recent chloroacetanilide CAG cumulative risk assessment, cumulative risk is not of concern. A revised quantitative cumulative assessment was not conducted because the proposed amended use would not affect the cumulative risk results. Not only is acetochlor a very minor contributor to chloroacetanilide cumulative risk when compared to alachlor, but removing the exception for rotation to rice will only have a minor impact on acetochlor exposure since finite residues on grains, including rice, are unlikely. In the residue data cited/translated to support this petition, non-quantifiable residues were reported in wheat and sorghum grains.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity database for acetochlor includes two rat and two rabbit developmental toxicity studies and three reproduction toxicity studies in rats. As discussed in Unit IV.A., there was no evidence of qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in any of these studies

3. *Conclusion.* EPA has determined that the FQPA SF of 10X may be reduced to 1X for the acetochlor acute and chronic dietary risk assessment. That decision is based on the following findings:

i. The toxicity database for acetochlor is now complete. An immunotoxicity study has been reviewed and is acceptable/guideline. Immunotoxicity was not observed at the highest dose tested. The acute neurotoxicity (ACN) and subchronic neurotoxicity (SCN) studies have also been upgraded to acceptable/guideline based on acceptable positive control data and functional observational battery measures.

ii. Furthermore, EPA has determined that a developmental neurotoxicity study is not required since:

a. There is no evidence of increased susceptibility in the rat and rabbit in the prenatal and 2-generation reproduction postnatal studies.

b. Developmental effects were observed in the presence of maternal effects.

c. The effects observed in the neurotoxicity studies were only at high doses.

iii. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues or average residue levels derived from reliable field trials. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetochlor in drinking water. These assessments will not underestimate the exposure and risks posed by acetochlor.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to acetochlor will occupy <1 % of the aPAD for infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetochlor from food and water will utilize 6.2 % of the cPAD for infants <1 year old the population group receiving the greatest exposure. There are no residential uses for acetochlor.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no short-term adverse effect was identified, acetochlor is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Because no intermediate-term adverse effect was identified, acetochlor is not expected to pose an intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* The chronic RfD of 0.02 mg/kg/day will be protective of both non-cancer and cancer effects, including rat nasal tumors, thyroid tumors, and mouse tumors. Chronic dietary risks do not exceed the Agency's level of concern.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to acetochlor residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high performance liquid chromatography (HPLC) method with oxidative coulometric electrochemical detection (OCED)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acetochlor.

VI. Conclusion

Therefore, the acetochlor tolerances for crop groups 15 and 16 are amended to drop the exception for rice and rice straw, respectively.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001)

or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 15, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.470, revise the entries “grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, rice and wheat, straw” and “grain, cereal, group 15, except corn, grain sorghum, rice, and wheat, grain” in the table in paragraph (d) to read as follows:

§ 180.470 Acetochlor; tolerances for residues.

* * * * *

(d) * * *

Commodity	Parts per million
* * *	* *
Grain, cereal, forage, fodder and straw, group 16, except corn, grain sorghum, and wheat, straw	0.3
Grain, cereal, group 15, except corn, grain sorghum, and wheat, grain	0.05
* * *	* *

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